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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/749,972 12/28/00 BURNHAM

M GM10201-D1

025308
DECHERT
ATTN: ALLEN BLOOM, ESQ
4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA PA 19103

HM22/1015

EXAMINER

RAO, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED:

10/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary**Application No.**

09/749,972

Applicant(s)

BURNHAM ET AL.

Examiner

Manjunath N Rao

Art Unit

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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 December 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 2-10 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 2, 5-7, drawn to polynucleotides, host cell and process of making a polypeptide, classified in class 435, subclass 69.1.
 - II. Claim 3, drawn to a method of treatment of an individual, classified in class 424, subclass 94.5.
 - III. Claim 4, drawn to a process of diagnosing or prognosing a disease condition, classified in class 435, subclass 15.
 - IV. Claim 8, drawn to an immunospecific antibody, classified in class 530, subclass 380.9.
 - V. Claim 9, drawn to a method of screening agonists and antagonists, classified in class 435, subclass 4.
 - VI. Claim 10, drawn to an agonist/antagonist, classified in class 514, subclass 789.
2. The inventions are distinct, each from the other because of the following reasons:
 3. Inventions I and II, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used for making a recombinant protein as opposed to its use in the method of treatment of group II or as opposed to its use in the method of group III.
 4. Inventions I, IV and VI are patentably distinct from each other. The polynucleotide of group I, the antibody of group IV, and the agonist/antagonist of group VI each comprise nucleotide sequences, amino acid sequences and compounds of unknown chemical structure which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I polynucleotide in a hybridization reaction, the group II antibody in

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affinity purification of a protein and the antagonist as an inhibitor of a chemical reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

5. Inventions I and V are patentably distinct from each other. The polynucleotide of group I is neither made nor used in the method of screening compounds that affect the activity of the polypeptide. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

6. Inventions II, III and V are patentably distinct from each other. The method of treatment of group II, the method of diagnosing or prognosing of group III, and the method of screening for agonists/antagonists of group are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

7. Inventions IV and II, III, V are patentably distinct from each other. The antibody of group IV is neither made nor used in the method of treatment of group II or the method of diagnosing of group III or the method of screening for agonists/antagonists. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

8. Inventions VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the chemical compound can be used for inhibiting a biological reaction under in vitro conditions as opposed to its use as a method of treatment of an individual.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. A telephone call was made to Tom Deibert on 10-11-01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao, Ph.D.

October 12, 2001



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600